K093862

510(k) Summary

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MAY - 6 2010

Official Contact: David Zhang

Date the Summary was prepared: 11-Dec-2009

Proprietary or Trade Name: CAREvent Handheld CPAP System

Common/Usual Name: CPAP device

Classification Name: Powered emergency ventilator (21 CFR 868.5925, product code: BTL) and Positive End Expiratory Pressure Breathing Apparatus (21 CFR 868.5965, product code: BYE)

Device Class: Class II

Classification Panel: Anesthesiology

Predicate Devices:

CAREvent ATV+ Transport Ventilator
- Manufactured by O-Two Medical Technologies Inc.
- 510(k) number K051469

MACS CPAP System
- Manufactured by Airon Corporation
- 510(k) number K080692

PortO_2Vent CPAP Oxygen Delivery System
- Manufactured by Emergency Respiratory Products
- 510(k) number K021520

Device Description:

The proposed CAREvent Handheld CPAP System is a pneumatically powered device designed to provide CPAP (Constant Positive Airway Pressure) to spontaneously breathing patients who require respiratory support. The patient can breathe spontaneously through the

device while the device provides constant positive airway pressure via a face mask. It has only one control for the adjustment of CPAP pressure from 0 to 20 cmH_2O.
The device may be used in pre-hospital transport applications including accident scene, emergency rescue vehicles, hospital transport applications including emergency, surgery, post anesthesia/ recovery and air transport via helicopter or fixed wing.

The device is a restricted medical device intended for use by qualified medical personnel under the direction of a physician.

The main accessories for the proposed device are Patient Circuit, Face Mask and Airway Pressure Manometer. They are all disposable for single-patient use.

Indications for Use:
The CAREvent Handheld CPAP System is intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital (EMS) environments.

Patient Population:
Spontaneous breathing adult and pediatric patients require respiratory support.

Contraindications:
- Patients undergoing procedures with flammable anesthetic gases;
- Patients undergoing hyperbaric treatment.

Summary of Technological Characteristics:

Technological Characteristics	CAREvent Handheld CPAP System	CAREvent ATV+ Ventilator (K051469)	MACS CPAP System (K080692)	PortO_2Vent CPAP (K021520)
Intended Use	Provide CPAP for spontaneous breathing patients require respiratory support	Pulmonary resuscitation during respiratory and/ or cardiac arrest. The CPAP subsystem provides CPAP for spontaneous breathing patients	Provide CPAP for spontaneous breathing patients via mask or endo-tracheal tube	Provide CPAP for spontaneous breathing patients via mask
Environments of use	Hospital, pre-hospital (EMS) environments	Pre-hospital, intra-hospital and inter-hospital transport	Hospital, pre-hospital (EMS) and sub-acute/ alternate site facility environments	Hospital, pre-hospital (EMS) environments
Patient population	Spontaneous breathing adult and pediatric patients	Non-breathing and Spontaneous breathing patients (body weight above 5 kg)	Spontaneous breathing adult and pediatric patients	Spontaneous breathing adult and pediatric patients

Operating principles	Pneumatic, demand flow system	Pneumatic, demand flow system	Pneumatic, demand flow system	Pneumatic, demand flow system
Input pressure	45 to 87 PSI	45 to 70 PSI	40 to 70 PSI	40 to 70 PSI
Patient circuit	Tubing with external expiratory valve, manometer and mask	Tubing with external expiratory valve and mask	Tubing with external expiratory valve and mask	Tubing with external expiratory valve and mask
Enclosure	Rugged, lightweight	Rugged, lightweight	Rugged, lightweight	Rugged, lightweight
Displays	Manometer	Manometer	Manometer	Manometer
Safety features	Internal high pressure release (at 40 cmH_2O), anti-suffocation valve on patient valve port	Internal high pressure release, anti-suffocation valve	Internal high pressure release (at 42 cmH_2O), anti-suffocation valve	Internal high pressure release (at 35 cmH_2O), anti-suffocation valve
Patient support modes	CPAP	IMV, CPAP	CPAP	CPAP
Peak Flow on Demand (L/min)	120	> 100	140	100
CPAP levels (cmH_2O)	0 - 20	0 - 20	0 - 20	0 - 20
Internal oxygen control	Pure oxygen only	2 position, 100% or 60%	2 position, 100% or 65%	Pure oxygen only
Materials in gas pathway	Identical to CAREvent ATV+ ventilator	Cleared in K052469	Unknown	Unknown
Accessories	Disposable patient circuit with mask, head strap, manometer, oxygen hose	Disposable patient circuit with mask, head strap, oxygen hose	Disposable patient circuit with mask, head strap, oxygen hose	Disposable patient circuit with mask, head strap, oxygen hose

Summary of Non-Clinical Testing

The essential performance of the CAREvent Handheld CPAP System has been comprehensively tested as per requirements of ISO 10651-5:2006 and are summarized as follows:

Summary of Bench Testing - CAREvent® Handheld CPAP System

Scope		Standard applied/ Acceptance criteria	Testing Org.	Test Result	Title of Test Report
Performance	Safety & Essential Performance	ISO10651-5:2006 Product Specifications	O-Two Medical	Comply	ISO10651-5:2005 checklist

	Patient Valve function after contamination	ISO10651-5:2006 Clause 6.1.1	O-Two Medical	Comply	Functional Test of CARevent CPAP after Contamination with Vomits
	Function Test after Reassembly	ISO10651-5:2006 Clause 6.1.3	O-Two Medical	Comply	Function Test After Reassembly
	Mechanical Shock	ISO10651-5:2006 Clause 6.3.1, 6.3.3	O-Two Medical	Comply	Drop Test/ Immersion in Water of CAREvent CPAP
		ISO10651-5:2006 Clause 6.3.2	O-Two Medical	Comply	Splash-proof Test
	Delivered oxygen concentration	ISO10651-5:2006 Clause 7.1.1	O-Two Medical	Comply	Delivered Oxygen Concentration of CAREvent CPAP
	Inadvertent PEEP & Continuing Expiratory Pressur	ISO10651-5:2006 Clause 7.1.3, 7.1.4	O-Two Medical	Comply	Inadvertent PEEP & Inadvertent Continuing Expiratory Pressure of CAREvent CPAP
	Dead Space	ISO10651-5:2006 Clause 7.1.5	O-Two Medical	Comply	Dead Space of CAREvent CPAP
	Pressure limitation	ISO10651-5:2006 Clause 7.2.4, 7.2.5	O-Two Medical	Comply	Pressure Limitation of CAREvent CPAP
	Demand Valve	ISO10651-5:2006 Clause 7.2.9	O-Two Medical	Comply	Demand Valve Function of CAREvent CPAP
	Durability of Markings	ISO10651-5:2006 Clause 8.2.2	O-Two Medical	Comply	Durability of Markings
	Inspiratory & Expiratory Resistance	ISO10651-5:2006 Clause 7.1.2	O-Two Medical	Comply	Resistance of CARevent CPAP to Spontaneous Breathing
	Expiratory flow characteristics	Adequatly to reduce carbon dioxide rebreathing	O-Two Medical	Comply	Expiratory Characteristics Test
	Static pressure testing	+/- 10%	O-Two Medical	Comply	Static Pressure of CAREvent CPAP
	Accuracy of pressure gauge	+/- 4% of the full range	O-Two Medical	Comply	CAREvent CPAP Pressure Gauge Accuracy Test
	Environmental	ISO10651-5:2006 Clause 6.2	BET Service Inc. / O-Two Medical	Comply	CPAP Unit Environmental test- Mar.25-26, 2010 Nov. 2009
Vibration/ Shock	**Sinusodial vibration**	IEC60068-2-6 Test Fc	Exova	Comply	Vibration & Shock Testing on CAREvent handheld CPAP System Report # 10-03-C0058
	Random vibration	IEC60068-2-36 Test Fdb		Comply	
	Bump	IEC60068-2-29 Test Eb		Comply	

Based on the above Non-Clinical testing results, the CAREvent Handheld CPAP System performs as intended according to its performance specification. Positive results from the Vibration and Shock testing also indicated that safety and efficacy of the device will not be adversely affected during transport and storage .

Substantial Equivalence:

The CAREvent Handheld CPAP System shares substantial equivalency with the MACS CPAP System and PortO_2Vent CPAP Oxygen Delivery System as follows:

- All devices have the same intended use as well as target patient population;
- They are all pneumatic controlled;
- They are all designed with the same operating principles;
- The essential clinical function of each device is significantly similar;
- The range of clinical function of each device is similar or significantly overlap;
- The accessories for all the devices are similar.

The CAREvent Handheld CPAP System also uses the similar components as the CPAP sub-system inside CAREvent ATV+ Ventilator. So the materials in gas pathway of CAREvent Handheld CPAP System are identical to the materials of CAREvent ATV+ which had been cleared in K052469.

Although clinical testing was not performed on the CAREvent Handheld CPAP System, safety and efficacy of the device are established through the non-clinical testing. There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

Conclusion:

The proposed device is substantially equivalent to the predicate devices, K051469, K080692 and K021520.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 6 2010

Mr. David Zhang
Quality Assurance Manager
O- Two Medical Technologies, Incorporated
7575 Kimbel Street
Mississauga, Ontario
Canada L5S 1C8

Re: K093862
Trade/Device Name: Carevent Handheld CPAP System
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator, Positive End Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BTL, BYE
Dated: April 26, 2010
Received: April 30, 2010

Dear Mr. David Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: CAR*Event* Handheld CPAP System

Indications for Use:

The CAR*Event* Handheld CPAP System is intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital (EMS) environments.

Prescription Use __X___ AND/OR **Over-The-Counter Use** _____
(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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